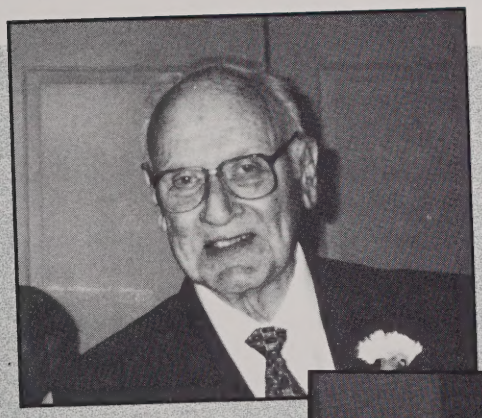
Bulk Rate
U.S. Postage
PAID
Springfield, MA
Permit No. 369

Hampden Hippocrat

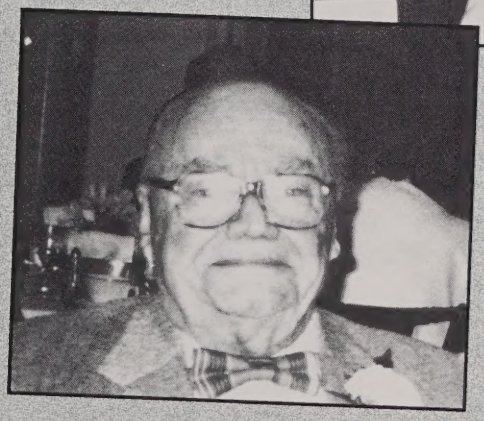
SUMMER 1997



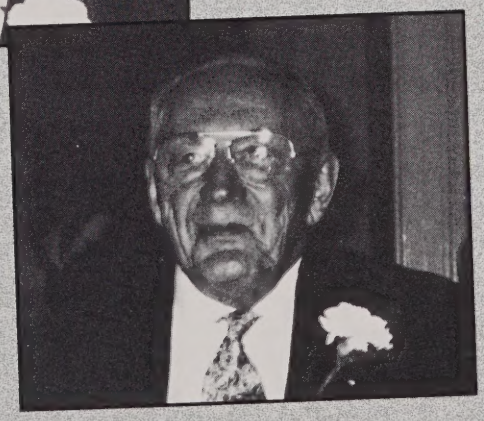
▲ Dr. Samuel Potsubay

▲ Dr. Bernard Bloom

Dr. Gerald Halton ▶



▲ Dr. Edward Halton



▲ Dr. Charles Diamond

50 Years in Medicine

The Hampden Hippocrat
1111 Elm Street
West Springfield, MA 01089

ADDRESS CORRECTION REQUESTED

Does Your Time Stretch Out of Control?

Why struggle to compete for operating room time at an over booked hospital? Physician friendly, Noble Hospital's new Center for Surgical & Ambulatory Care is the first of its kind in Western Massachusetts. This state-of-the-art surgical facility utilizes the latest technology designed for maximum efficiency. You'll work faster and easier, with more flexibility in handling your patient load. All in a relaxed, professional environment.

Of course, your patients will love us too. We're in a convenient, quiet, community based location with easy access for your patients west of the river with *plenty of free parking.*

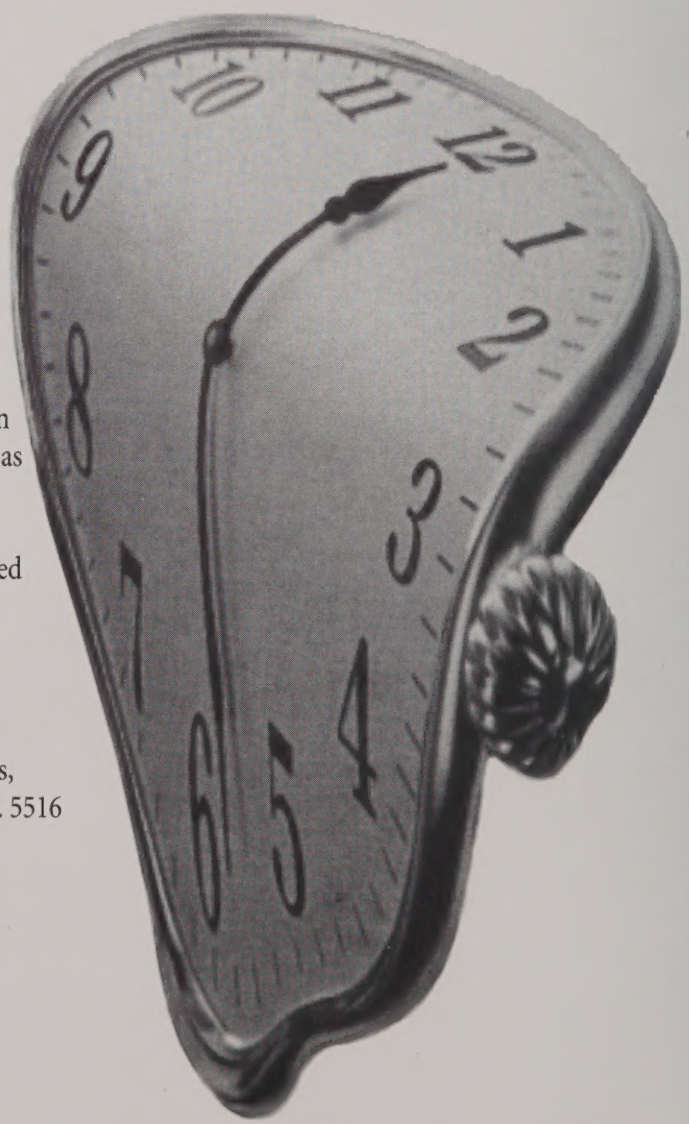
We offer a facility designed with the physician in mind:

- A 20,000 square-foot state-of-the-art facility
- Four operating suites
- Four minor procedure rooms
- State-of-the-art ICU
- Laser and laparoscopic surgeries
- Top-of-the-line Anesthesia on site
- Board-certified intensivists on staff
- ACLS certified OR and PACU nurses
- Private patient rooms in the Phase II recovery area

Because your time is better spent with patients and not on administrative matters, we try to make the whole process as easy as possible:

- Contracts with all major managed-care plans
- We are a low cost provider to better help you in a capitated environment
- Simplified admitting for easy check-in and out
- Easy commute avoiding city traffic
- Safe, secure facilities

For more information or to arrange a tour of our facilities, please contact Dr. Richard Douglas at 413-568-2811 • Ext. 5516



NOBLE HOSPITAL

Affiliated with University of Massachusetts Medical Center
A member of Noble Health Systems
115 West Silver Street, Westfield, MA 01086

NOBLE HOSPITAL'S CENTER FOR SURGICAL AND AMBULATORY CARE

Carol L. Nystrom
Executive Secretary

Donna Clements
Membership Secretary

OFFICERS

Daniel Dress, *President*
Marc A. Linson, *President-Elect*
Robert C. Shepard, *Vice-President*
Jean R. Talati, *Secretary*
Alan M. Harvey, *Assistant Secretary*
John R. S. Remsberg, *Treasurer*

EXECUTIVE COMMITTEE

Daniel Dress
Marc A. Linson
Robert C. Shepard
John J. Papale
John R. S. Remsberg
Jean R. Talati
Alan M. Harvey
Mark J. Mullan

1997
Stephen V. Hall
Timothy K. Fitzpatrick

1998
R. Gopal Malladi
James K. Wang

1999
J. Michael DeCenzo
Claudia L. Koppelman

CHAIRPERSON OF COMMITTEES

R. Gopal Malladi, *Auditing*
Mark J. Mullan, *By-Laws*
Michael H. Rosen, *Education*
Lorne C. Smith, *Insurance*
Stephen A. Metz, *Legislative*
Kenneth M. Frankel, *Mediation*
Mark J. Mullan, *Medico-Legal Affairs*
Roland F. Stebbins, *Medico-Religious Affairs*
Robert V. Chircop, *Membership*
Francis J. Riley, *Nominating*
Francis J. Riley, *Public Health*
Alicia O.M. Ross, *Public Relations*
Bernard Bloom, *Scholarship*
Dennis S. Gordan, *Tax Supported Medical Care*

DELEGATES

Augusto G. Asinas
Charles W. Cahill
Robert V. Chircop
Dennis S. Gordan
Peter S. Greene
Stephen V. Hall
Alan M. Harvey
Samuel Hellerman
Francis D. Horrigan
Barbara G. Jericho
Jeffrey L. Kaufman
Joseph P. Keenan
Claudia L. Koppelman
Jose E. Llorens
Gerda S. Maissel
Yash P. Malhotra
R. Gopal Malladi
Stephen A. Metz
Mark J. Mullan
Catherine E. O'Connor
John J. Papale
David J. Pierangelo
Francis J. Riley
Michael H. Rosen
Alicia O. M. Ross
Robert C. Shepard
Gregory A. Slachta
Philip B. Stoddard
James K. Wang
Murray Watnick

EX-OFFICIO

James J. Siragusa, Jr.
Daniel Dress
Jean R. Talati

THE
Hampden Hippocrat
SUMMER 1997

In This Issue

President's Message 4

Annual Meeting 7

American Medical
Accreditation Program 13

Health Law and Ethics 14

New Members Welcome 22, 23

In Memoriam 24, 27

Short Notes 28

The official bulletin for The Hampden District of the Massachusetts Medical Society. Founded in 1942 by Edward P. Bagg, Jr., M.D. and William A. R. Chapin, M.D.

PAST EDITORS: Max Millman, M.D., John C. Ayres, M.D., Walton E. Stevens, M.D., Vivian M. Purdy, Walter J. Pacosa, M.D., William J. Baker, M.D., Terry D. Ryan, M.D., Nicholas P. W. Coe, M.D., Donald J. Higby, M.D.

EDITORIAL BOARD: Brigid K. Glackin, M.D., Dennis S. Gordan, M.D., Francis D. Horrigan, M.D., John J. Papale, M.D.

THE HAMPDEN HIPPOCRAT is published quarterly by The Hampden District Medical Society West Springfield, MA. Acceptance of Advertising in the HIPPOCRAT does not imply endorsement. The opinions expressed in this bulletin are those of the writers and do not reflect the official viewpoint of the Hampden District Medical Society unless so stated. All communications should be addressed to Carol L. Nystrom, Hampden District Medical Society, 1111 Elm St., West Springfield, MA 01089: Telephone: 736-0661. To be assured of uninterrupted delivery of THE HAMPDEN HIPPOCRAT, notify us in advance of an address change and include your zip code number.

"Poor Grace, she's really gone over the hill." No one would say it ... but I knew it's what they were thinking. **"I could see it in other people's eyes ... and I knew it in my heart. Something was wrong. Finally, my son stepped in and called the Genesis ElderCare℠ Line. Genesis found out it was my medications that were making me, well, goofy. At Genesis, they saw me as a real person, not a chart ... and really listened. That's why they got it right.**

"It wasn't just my medication they adjusted. It was my attitude. Now, I don't just think I'm better ... I'm better than ever!"

At Genesis ElderCare℠, we understand that everyone ages differently ... because we specialize in understanding the challenges of aging — and how to meet them successfully. We help people realize their full potential — and achieve a Full Life — through a network of people, places and programs. Find out for yourself. Call the Genesis ElderCare℠ Line today at ***800-337-1540, Dept. 70.***

Genesis ElderCare℠
ElderCare for a Full Life℠

Class "A" Medical Space
---- FOR LEASE----
5200 s.f. single story
medical facility

Park Ave. and Union St.
AAA Location
West Springfield, MA.

BUILDING FEATURES:

a. 5 physicians offices
b. 10 examining rooms
c. large waiting room
d. laboratory
e. business office
f. nurses station
g. children's area
h. 5 bathrooms
i. generous parking
j. high visiblity

and more

For more information please contact:

Joel Kahan
Plaza Mall Associates
(203) 397- 0275

From The Editor

At the Annual Meeting Dr. Joel Neuschatz, medical director of Aetna U.S. Healthcare, provided his thoughts into some aspects of managed care. I felt his remarks were insightful because he was an internist in private practice for 21 years and only recently took the position as medical director. As a result, he has a unique perspective from more than one vantage point. While he feels managed care is "a work in progress", he was able to give good reasons as to why it has become so successful. His remarks are summarized in this issue.

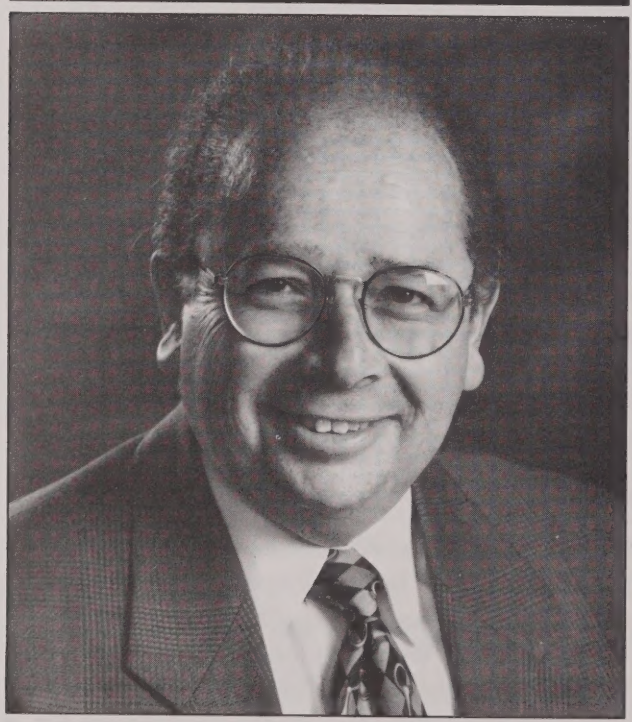
The Annual Meeting also marked the end of Dr. Dan Dress' term as president of our society. Dan has worked tirelessly on our behalf and selflessly donated his time to the business of the society. A notable accomplishment is the successful adoption by the Massachusetts Medical Society of a resolution advocating a single HCFA rate for the entire state. While this initiative still has a long road ahead before it becomes reality, the endorsement of the state society is an important first step. If HCFA ultimately adopts this payment rate, doctors outside of Boston will continue to receive the same reimbursement as those in the immediate Boston area! (Currently, HCFA is proposing that doctors practicing in three counties in and around Boston receive more reimbursement than those outside of these 3 counties). Dan was a major mover for the continuation of a single rate, and we all owe him a debt of gratitude. At the same meeting, Dr. Marc Linson was installed as our new President, and Dr. Robert Shepard as our new President-elect, and Dr. Claudia Koppelman as Vice-President. We wish them the best of luck.

On our cover, we are pleased to honor our fifty year members. They are: Dr. Bernard Bloom, Dr. Charles Diamond, Dr. Edward Halton, Dr. Gerald Halton and Dr. Samuel Potsubay. Their attendance at the Annual Meeting was a reminder of the rich heritage of the Hampden District Medical Society. Dr. John Appel, Dr. Roger Dudis, Dr. Field Leonard and Dr. James Visconti were also honored as fifty year members this year, although they were unable to attend the Annual Meeting. Congratulations to all of them.

John J. Papale, M.D.
Editor

The Battle of Beacon Hill

This past presidential year provided me with several opportunities to be interviewed by media reporters, and occasionally be quoted in the newspaper or have a sound-bite on radio. This,



Daniel Dress, M.D., President

in turn, provided some of my patients, who read or heard my remarks, with opportunities to afford me their feedback.

Some of the issues, about which I commented, and subsequently prompted patient response, include the following:

• Physician unions - (This question was prompted after a group of podiatrists came out in favor of unionization.) I spoke on behalf of this concept, along with modification of the federal anti-trust laws, because it would provide doctors with a vehicle which could more effectively negotiate with the larger insurers.

• Physician profiling - I said that this is one useful tool for patients, but there are other more important measures. And I further remarked that doctors are being exclusively singled out, apart from other professions - why not priest or lawyer profiling?

• Patient choice of physician - Clearly, increased flexibility for a patient to select a doctor, in managed care plans, needs to be addressed.

• Physician assisted suicide - I was quoted as saying that physicians have a higher ethical responsibility, regardless of what the law will allow. And if assisted suicide is enacted, it has the potential of ripping apart the trust embodied in the patient-physician relationship.

All of these topics are controversial. Consequently, I was quite surprised at the overwhelming support relayed to me by my patients, reacting to each issue. But in retrospect, I should not have been surprised. Patients want to be involved in issues relating to their health care, and know that we physicians are their advocates.

It would be trite of me to re-iterate the liturgy which we have been told repeatedly over the years: We as physicians, can effect changes in health care, for the betterment of our patients, by taking the time to work within the legislative process - by calling and writing our legislators concerning the important medicine-related

issues, and financially supporting those who concur with our positions.

But after all the feedback I have received from patients during the past year, something of even greater importance is abundantly clear to me now. We as physicians can best effect change by more actively involving our patients into these discussions. I had always been rather reluctant and a little embarrassed to discuss topics with patients at the time of an office visit, if the discussion didn't have something to do with the patient's chief complaint. And I believe that most doctors think along the same lines. However, I now firmly believe that patients want to be more involved with the important and controversial health issues of the day. Moreover, they want to speak out and give their input, and want us to get them involved in these issues. They look to us for guidance, and want to discuss those issues with us their doctors. Patients, in general, desire to take control of their lives, and seek means to take charge of their health. (A corollary to this is the patients' burgeoning interest in alternative medicine.)

Physicians ought to more frequently query our patients for their opinions and discuss these kinds of issues with them *in the office.* That time, it seems to me, is a very appropriate opportunity to align ourselves in our common interest: their health care. Our patients are our greatest allies. Together we can generate a stronger and larger voice to our elected officials. We can utilize the physician-patient relationship to develop a new association, an "advocate-ally army". Doctors' Day on Beacon Hill was a great event last March. But can you imagine the power of the vision of this army of doctors *and* patients storming Beacon Hill together, speaking with a voice so loud and clear and singular that no legislator can ignore? ■

Take two and call us in the morning.

For private and commercial banking, SIS Bank is just what the doctor ordered. Especially now that your personal and professional successes have brought on additional demands. Your financial requirements are likely more involved than ever. Yet your time is at a premium. Well, SIS Bank has the remedy.

1 SIS Private Banking

- Personal, confidential access to all the banking services you need.
- Designed to make every financial transaction as smooth as possible.
- Unlike representatives based in Boston Providence, and Hartford, your SIS Banker is always right in your neighborhood.

For more information, call Beth Mineo at 748-8270.

2 Commercial Services

- Your experienced, local lender.
- Your source for the best loans with fixed and variable rate options: to buy into a partnership, to expand your business, to purchase equipment, to buy commercial property.
- Lines of credit.
- Corporate deposit products.

For more information, call Dave Glidden at 748-8274.

SIS Bank

Member FDIC/DIF
Equal Opportunity Lender

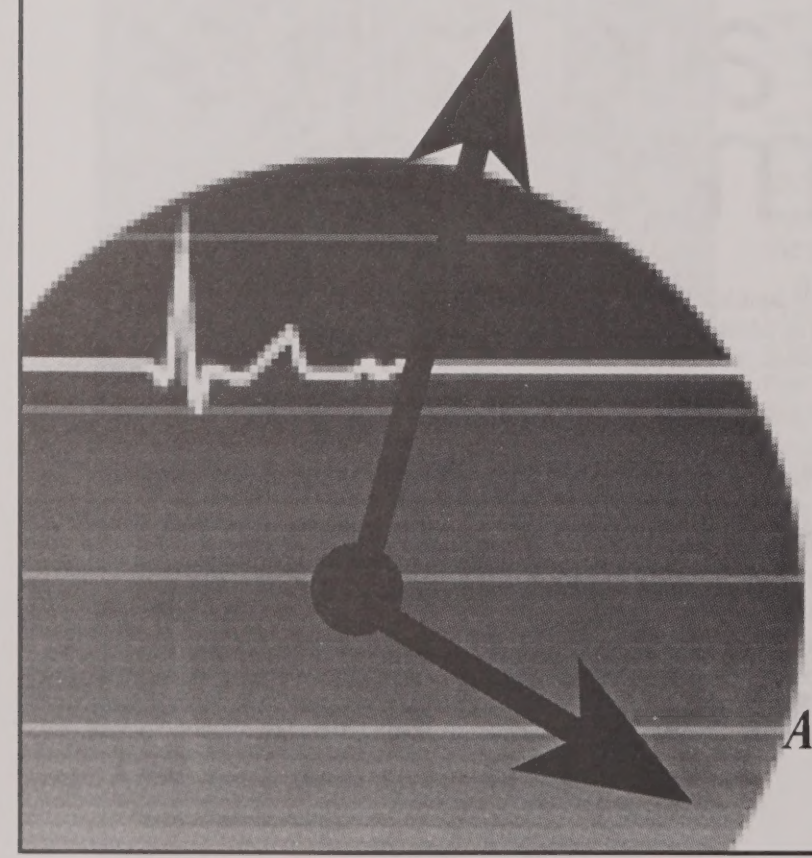
SIS Bank is the trademark of Springfield Institution for Savings.

TIME IS RUNNING OUT!

Have you given your patients the message that time can save their lives?

Don't delay – Call today for FREE patient brochures and videos.

Call 733-4401.



HEART ATTACK REACT

Thoughts Into the Aspects of Managed Care

by Joel Neuschatz, M.D.

The annual district meeting was held April 15, 1997 at the Colony Club in Springfield. Dr. Joel Neuschatz, medical director of Aetna U.S. Healthcare was the featured speaker. He provided some observations of why he left the private practice of internal medicine to become involved in managed care, and made it clear that his remarks were his personal opinions and not those of his company or any other organization. His comments are summarized below.

I was an internist and took care of patients in a small New England town in central Massachusetts for over 21 years. It was never my intention to be an insurance executive or administrative physician. Through a series of circumstances, fate brought me to this position. My partner was a part time administrator for a local HMO. He in turn was recruited for the medical director's position for U.S. Health Care when they came to New England and he took that job as a full time physician. He gave me the opportunity to work for that company in a part-time position, one day a week while I was still practicing. He in turn took a full time position with Blue Cross/Blue Shield. The position opened up at U.S. Healthcare. It was offered to me, and I was very ambivalent about it. I said to myself, "Do I really want to do this?" I'd been practicing for a while, certainly not as long as the admirable people that Dan honored tonight, but I felt I had worked for quite a long time with some frustrations and I was ripe for a change, but I didn't want to give up patient care. I went down for my interviews at U.S. Healthcare at their corporate headquarters in Philadelphia and was interviewed by several of the corporate medical directors down there. One doctor especially has really been a role model for me. He is a very wise and experienced physician. He was speaking to me at the interview and he said, "Why do you want this job, Joel, why do you want to get into this?" And I said, "Well, to tell you the truth, I am not sure that I do. I really only see myself as a practicing physician. I really only want to take care of patients, and even though the industry of managed care and the changes in medicine are stimulating and interesting and challenging to me, I would really feel terrible if I had to give up patient care and give up taking care of patients." And he looked at me and said, "Why do you think that you have to give up taking care of patients or working with patients and doing good for patients if you took this job?" He said, "This is an opportunity to do your job and to practice your skills on a higher level, on a broader level. As a physician in practice, you work with patients one at a time, you take care of their problems, you try to serve their needs. You have the opportunity by taking this job to work with hundreds of patients at a time, thousands of patients at a time and to do things and to make changes that can positively influence their lives and their health, and it can be very, very satisfying if you look at it in those terms." This has really been my guiding light in managed care and it's what really motivates me. I still feel that my ethics and my values are intact as a physician. And this is not unusual among my peers, believe it or not, in managed care. I consider myself a patient advocate. I don't think that my primary job as a medical director of an HMO is to save every nickel in the system and to nickel and dime every physician and to deny access and services to patients. In actuality, that is not only bad medicine, but bad business. It is counterproductive.

This should be a partnership so we can serve our patients and put the medical profession back in the status that it belongs.

Continued on next page

Annual Meeting

Continued from page 7

Premature discharges from the hospital, denial of services, only leads to dissatisfied patients, poor outcomes, more complications, more morbidity, more mortality and failure of managed care companies.

When I think about managed care and about medicine, I think of my own perspective on what's happened over the course of my career. I think I'm in an interesting position as we all are - we've all seen tremendous changes in the medical profession. But I think that my generation specifically has lived in the eye of the hurricane and we have really seen enormous changes occur in our profession during the time that we have been practicing. I graduated from medical school in 1968 and I entered practice in 1974. When I look back on the past, I consider that the golden age of medicine. When I came into medicine in 1974, the profession seemed just perfect. It was just exactly what I had aspired to when I was a child. Medicine was affordable. People could actually afford to see their doctors. It wasn't a burden on them. Medicine was primary care based. Most doctors were practicing primary care. Specialists were obviously available and functioning appropriately. Medicine was a fee for service system. When I first started in practice, I didn't know what to charge for a fee. I asked some of my colleagues in town and they said, well, most docs are charging ten bucks, but I think you should charge eleven because that's where we're going in the next year. I said gee, eleven dollars - that sounds a little steep to me - they said don't worry it's reasonable. And that was my initial office fee - eleven dollars a visit - most of my patients paid in cash - over the counter. There was no insurance. There were no referrals. There were no approvals. At the end of the week, I took my little deposit bag to the bank and put my deposit in the bank and went home and I was satisfied, and my patients were satisfied, and the world seemed to be right. Doctors at that time were well respected and compensation seemed fair and the patients were satisfied. Everything seemed to be in good shape. Unfortunately, that didn't last.

Entrepreneurial medicine developed. Doctors became businessmen. This was something that didn't exist before that. The doctors kept finding different ways to practice medicine and practice business. Surgi-centers, ambulatory care centers, radiology facilities, laboratory facilities, partnerships of various kinds, doctors behaving like businessmen. The legal profession changed as the medical profession changed. Opportunities for enormous malpractice suits became prevalent and headlines talked about multi-million dollar malpractice suits and doctors found their malpractice insurance escalating. In one year my malpractice premium went from twelve hundred dollars to seventy-five hundred dollars. You can be sure my office fee wasn't eleven dollars next year. It started going up and it kept going up.

The nineties came. The period of transition was behind us and the crash arrived. Health care became unaffordable. Ambulatory care became completely unaffordable without insurance coverage. My average office visit at that time was over forty dollars. A 400 percent increase from the time I started practice twenty years before. I wasn't out of line - I was charging a little bit less than my colleagues. I thought I still had a conscience.

Insurance premiums were excessive. Excessive for patients. They couldn't afford their insurance. Blue Cross virtually had a monopoly and every year the premiums went higher and higher until people simply couldn't afford their insurance anymore.

Something had to be done. Things weren't working. Necessity is the mother of invention and managed care arrived to try to fill that void. It's an imperfect solution. It's a work in progress. There's still much to be done, but the situation was intolerable before this happened.

But before we have any solutions, we have to identify our problems. We have quite a list of problems and if managed care is going to fulfill its promise, it must solve these problems. What are these problems - they are known and obvious to all of us.

First of all, patients must have choice. They want to see the doctor of their choice when they want to. They have to have access. They want to go to the facility that they are comfortable with and have confidence in. Barriers to care must go down. People can't be excluded because of preexisting conditions or other barriers. Denial of services has to be a big issue. People will not tolerate being denied care that they need and neither will their doctors who have to be their advocates. The for-profit status of insurance institutions has to be investigated. I work for a for-profit company. I can talk all night about the pros and cons and the propriety of that situation, but this is an important issue and this has to be addressed and resolved so that we can go forward and put

this behind us. Long term care has to be addressed. We can't just ignore this. Our population is aging and there is an enormous commitment necessary to take care of the aging population. Education and research cannot be forgotten. We have to educate our students and we have to have the top students as we've always had to maintain our status as a profession, and we have our commitment to research so that our profession grows. We have to take care of care for the disadvantaged. We can't exclude these people and just have a segment of the population benefit. There has to be equitable compensation for doctors. Doctors deserve to be paid adequately and appropriately for the care that they render.

So those are the problems. What's the promise? What's the solution? How can we do this? Well, I can give you some examples of positive things that are being done, but I remind you that this is a work in progress. We're not finished and we don't have it down "pat" yet.

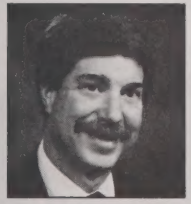
The first thing that we have to do is create what I call the alignment of interest. So far, I have not spoken of the company that I work for and have not even mentioned that company hardly, but what I'm going to say now relates to how we do things. But this is not just the only way or the best way of doing things, but we have to think of a change in the way that we deliver health care so that everybody benefits. In the old fee for service system, even though patients got good care, there was a reward for quantity of care and for intensity of care. The more care that was given, the more money that was generated for the doctors, for the hospitals, for the institutions and that was an inflationary problem and it was just not sustainable. What we need is a way to align interests so that we put the patient first. If the patient comes first, we have to have a system so that when the patient benefits, the doctor benefits. And when the patient and the doctor benefit, then the company that provides the insurance will benefit as a third party. Only when all three of those are aligned, will the system work properly.

Let me tell you how my company does that just as an example. Not as the model for future health care, but as just one way to approach this. We pay primary care physicians on a capitated basis. Capitation, like for profit status, is another topic for another day and there are certainly pros and cons to that. There are the issues of incentives and the issue of risk and the issue of conflict of interest and these are all valid. We pay a basic capitation fee and then what we do is we pay an incentive to doctors for the delivery of quality.

Continued on next page

ARE YOU CONCERNED ABOUT

- the impact of the medicare-medicaid anti-kickback regulations on your daily practice?
- issues relating to the sale of your practice
- structuring employment, partnership and shareholder agreements for group practices?
- malpractice claims due to inadequate informed consent?
- reducing estate taxes, and protecting assets from creditors' claims?
- providing for the orderly disposition of your practice in the event of death or disability?



Attorney
Arthur W. Price

Arthur W. Price and Michele J. Feinstein, partners in Cohen, Rosenthal have more than twenty-five years of combined experience in representing area physicians in their practices and individually. They counsel solo and group practices in their day to day business as well as in their planning for growth or extraordinary concerns. They also advise physicians on personal and family problems.

Call Arthur W. Price or Michele J. Feinstein to discuss your practice or personal concerns. We're here to help.

Attorney
Michele J. Feinstein

COHEN, ROSENTHAL P.C.

ATTORNEYS AT LAW

One Monarch Place, Suite 1300, Springfield, MA 01144-1001
Tel.: (413) 781-0472 Fax: (413) 734-9013

Annual Meeting

Continued from page 9

Not for the withholding of care. Not for the saving of cost, but for the delivery of quality. How do we measure quality? We measure quality based on preventive care - we do measurements of prevention by looking at charts, looking to see that children are immunized, women get mammograms and pap smears, colo-rectal exams are done, adults are screened for cholesterol. We do surveys of all of our patients every year to be sure that they are satisfied with their access to care and the quality of care that they receive. We give credit to doctors who participate in continuing education programs and we give extra credit to those doctors who give extra comprehensive care, provide care at extended hours or extra procedures in their office so that their patients have extra access and extra availability of care. By doing this, what we hope to do and what we intend to do, is put the patient first in the equation. Our job is to advocate for the patient - to advocate for their health and their preventive care, and we will reward the primary care doctors who provide that good quality care and that good comprehensive care. We'll pay for that, so the doctor is now motivated not to give more care or more intensive care but to give more preventive care and more health promotion and we'll pay that doctor to do that. When the patients are healthier and the population is healthier, then the insurance company will make money and will make money because that population of patients will be healthier and they'll be in the emergency room less often and will be in the hospital less frequently and they'll be disabled less often and they won't have to go to nursing homes at such an early age and they won't have to miss work so frequently. And maybe this is "pie in the sky" kind of reasoning, but this is the kind of thinking that has to be done. We have to advocate for our patients. We have to pay for that. We have to compensate for good care and that's the way a managed care company can profit. Not by simply restricting cost and restricting access. Managed care has certain other benefits that traditional medicine does not. Managed care requires doctors to be accountable in ways that individual physicians are not. We are scrutinized continually by an organization called the NCQA (National Committee on Quality Assurance), which puts us through rigorous evaluations every two years. We're required to report the data of the Hedus Coalition to prove that we're providing good preventive care for our patients. Accountability is an

For *Home Health* and *Hospice Care*

- 24 Hours A Day -- 7 Days A Week
- Certified for Medicare and Medicaid
- Licensed in Connecticut
- United Way Agency
- JCAHO Accreditation with commendation

VISITING NURSE ASSOCIATION & HOSPICE

Visiting Nurse Association and Hospice of Pioneer Valley, Inc.
50 Maple Street • P.O. Box 9058 • Springfield, MA 01102-9058
(413)781-5070 V/TTD

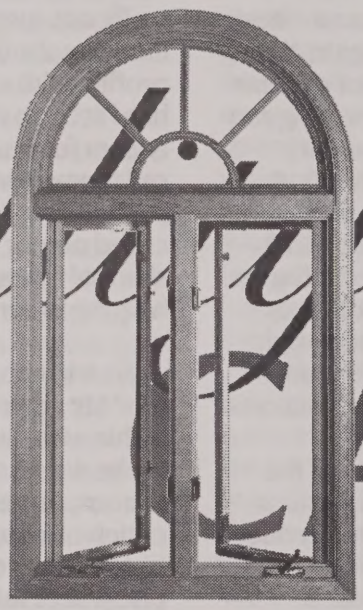
important element of managed care that's an advantage.

There's added value to managed care. The managed care companies have a stake in promoting good care for their patients, so they provide benefits that go beyond the traditional insurance benefits. Memberships in fitness clubs and smoking cessation programs and diet programs - this is all part of the alignment of interests. Again, the idea of making a healthier population of patients so that the company can do better in the long run. My company has a wholly owned subsidiary known as USQA (US Quality Algarhythms). A company we have put an enormous resource into in manpower and money. Three hundred individuals, physicians, statisticians, epidemiologists, information specialists, this organization does nothing but work up quality programs to implement to our patients throughout our network. In every single case where they've rolled out one of these programs, we've been able to demonstrate improvement in the health of the population that we served. We have programs in asthma care which have demonstrated reduced emergency room use and hospitalizations. Programs in congestive heart failure which showed increased quality of life. Breast cancer program which has demonstrated detection at an earlier stage and the same for colon cancer. Diabetic programs which allow us to identify retinopathy earlier and prevent blindness. In every situation we've demonstrated benefit to our population and in so doing, we've enhanced the status of our company. We have an organization known as HDIC, the Health Data Interchange Corporation, a sophisticated information system where we can apply information technology for the benefit of our patients and the doctors who work with us. We have an online system now where our patients can call in 24 hours a day, speak to a nurse and get health information. We can work with doctors to develop clinical pathways - electronic medical records - this is all in our interest. Healthier patients, more profitable doctors, advantages to the company.

Public initiatives must be undertaken to fund care for the under-served. A very difficult issue, but one we can't forget. How can we do this? I'm really not sure, but it comes back to sometimes thinking about this issue of for profit and not for profit health care institutions. When you look hard at them they're really not very different except for one very big difference. The ones that call themselves not for profit don't pay taxes. We pay millions of dollars in taxes. I think these so called not for profits ought to have paid their fair share of taxes and that money ought to go into helping to serve the underprivileged in the country.

So what conclusions can we reach from all of this? My advice is to maintain objectivity, to look at this with clear eyes, to reject the irrational. We're doctors, we're scientists, we are educated to accept scientific theory, yet managed care gets criticized continually based on anecdotes (I know a case where this happened, I know someone where this happened) that's not science. We have millions of patients under managed care. When we look at this with a cold eye we know that patients are getting good care and they are generally satisfied. We hear the exceptions and they are sometimes blown out of proportion. We have to correct the inequities, there's plenty of them. We're not doing this all right. We have to work together on this to straighten this out - to get this to work. Managed care is here to stay. This should be a partnership so we can serve our patients and put the medical profession back in the status that it belongs. We have to develop a cooperative partnership to accomplish these goals. ■

WINGATE
AT WILBRAHAM



quality CARE

LOOK INTO QUALITY CARE AT ITS BEST.

Wingate at Wilbraham has one of the finest reputations for providing short-term rehabilitation and long-term care in the area. With a deep commitment to providing care that is unparalleled, our compassionate, trained professionals can offer you individualized care for the following services:

~Rehabilitation Services
~Respiratory Management
~Complex Medical Management
~IV Therapy
~Cardiac Recovery
~Wound Management
~Post-Surgical Recovery
~Oncology
~Respite Care
~Orthopedic
~Stroke Recovery
~Pain Management
~Diabetic Teaching
~Hospice

We welcome you to look into the quality of Wingate at Wilbraham. For more information, please call (413) 596-2411.

WINGATE AT WILBRAHAM · 9 MAPLE STREET · WILBRAHAM, MA 01095

JCAHO ACCREDITED

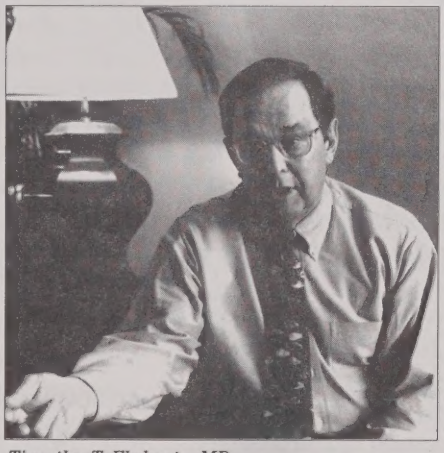
American Medical Accreditation Program: AMA Trustee, Dr. Timothy Flaherty, Discusses the Road Ahead

What was your reaction to the debate over AMAP at the AMA's Interim Meeting?
We had an interesting discussion. The American Medical Accreditation Program, "AMAP," is extremely important to physicians. I think there had been a communications deficit, as there always is when people are getting started with a new program. Sometimes all the information people are requesting is not available. The specialty societies, in particular, had reservations and hesitations about the program, but came away convinced that AMAP was something we should move forward with on a fast track. I am pleased that support for AMAP is gaining momentum.

AMAP is a massive undertaking. Why is it necessary to move ahead so quickly?
The timing is critical. If we don't get it done now, we will lose out to the health plans, commercial vendors and other groups who are waiting in the wings to take over. If we are going to have a national acquisition of data about physicians and physician performance, it should be done by physicians; not the government, not the insurance companies. The AMA and the Federation are the best professional organizations to take on the job. With the Federation's help, we are confident we can succeed, and keep standards for physician performance in the hands of physicians.

How were members of AMAP's Governing Body selected?
We sought from the start to fill the seats on AMAP's Governing Body with experts who represent the different viewpoints and experiences that AMAP will need to succeed. We solicited nominations from all state, county and specialty societies, and have filled the seats with individuals representing hospitals, managed care, accrediting organizations, voluntary health care organizations, employers, and consumers, as well as state, county and specialty societies. In addition, four at-large physician seats were added to ensure the broadest representation possible.

How will the Federation partner with the AMA on AMAP?
AMAP is a Federation program. Thus, the Federation will play a critical role throughout AMAP's design, implementation and operation. In fact, AMAP could not proceed without the Federation's expertise, participation, and support. For example, many state and county societies already play a vital role in credentialing and office site reviews. AMAP hopes to incorporate these existing programs and extend them to the national level so that the profession won't continue to be hassled by repetitive inspections when a single inspection will do. AMAP will result in less disruption of physicians' offices, medical records, and patient programs. It's a big plus.



Timothy T. Flaherty, MD

When will AMAP be up and running?
AMAP will be rolled out on a state-by-state basis. Massachusetts was selected as the initial implementation site because the Massachusetts Medical Society already has the necessary structural framework in place. A number of other states have volunteered to partner with AMAP in implementation of AMAP, and future states will be selected based on how far along each state is in terms of providing similar services to its members. Ultimately, AMAP will follow a natural progression adding more states and additional components as soon as feasible. We expect AMAP to be fully operational nationwide in four years.

What role will specialty board certification play in AMAP?
AMAP is a physician accreditation program. It is not a specialty board certification program. Obviously, if you are board-certified or recertified by your board, these factors will be included in your AMAP profile and should be. However, AMAP and board certification are separate programs serving separate goals. AMAP will be working very closely with the American Board of Medical Specialties and other certifying agencies so that board certification will be appropriately weighed in the AMAP accreditation decision. And, we believe the specialties have a lot to gain through participation in AMAP. They will have the opportunity to set the standards for their specialty instead of having them imposed by outside groups.

Are you confident that the House of Medicine will unite behind AMAP?
I believe medicine will unite behind AMAP–at least as much as the profession can unite behind any program of this scope and complexity. However, the commitment to the overall program is what's important. And, it will be AMAP's commitment to use Federation resources and actively involve the specialty societies which will make the acceptance of AMAP more meaningful.

You have been active in meeting with employer coalitions across the country. How has AMAP been received by them?
I serve as an advisor to the National Business Coalition on Health, and I have also been meeting with benefit managers. They could not be more enthusiastic. Benefit managers have been looking for a reliable way to identify quality. AMAP will be a big plus for them because it will provide a "Good Housekeeping Seal of Approval" that they can take to their employees and say "See, this physician, or this group of physicians, has met the highest standards of quality as established by a group of their peers."

So you believe that patients, as well as physicians, will benefit from AMAP?
Absolutely. Anytime the medical profession can establish a single, universally-recognized standard of quality, physicians everywhere will strive to meet that standard. AMAP will result in an improved evaluation process for physicians, less hassle for physicians, and improved quality of care.

Interview by Wendy Sue Morphew, J.D.

The Legal and Scientific Basis for FDA's Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco

David A. Kessler, M.D.; Philip S. Barnett, J.D.; Ann Witt, J.D.; Mitchell R. Zeller, J.D.; Jerold R. Mande, M.P.H.; William B. Schultz

It is both a privilege and a pleasure for me to introduce this special article. For it contains the highlights of all 650 pages of the key 1996 federal document on why cigarettes are drug devices, boiled down to a mere four pages. The author, Dr. David A. Kessler, and his colleagues are to be commended for their persistence and near success in the struggle to bring nicotine-containing- and addicting tobacco under the control of the U.S. Food and Drug Administration (FDA). While he has recently resigned from his all-important post of Commissioner of the FDA, Dr. Kessler already deserves to take his place in American medical history for his anti-smoking accomplishments. As a former resident myself of the cowboy-and-Indian country of the southwest, I would never want to have Dr. Kessler tracking me down! the way he did the tobacco industry executives--for which I sincerely congratulate him.

Francis J. Riley, M.D.
Chairman, Public Health Committee

On August 28, 1996 the U.S. Food and Drug Administration (FDA) asserted jurisdiction over cigarettes and smokeless tobacco under the Federal Food, Drug, and Cosmetic Act. Under this Act, a product is a "drug" or "device" subject to FDA jurisdiction if it is "intended to affect the structure or any function of the body." The FDA determined that nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" because nicotine causes addiction and other pharmacological effects. The FDA then determined that these pharmacological effects are "intended" because (1) a scientific consensus has emerged that nicotine is addictive; (2) recent studies have shown that most consumers use cigarettes and smokeless tobacco for pharmacological purposes, including satisfying their addiction to nicotine; and (3) newly disclosed evidence from the tobacco manufacturers has revealed that the manufacturers know that nicotine causes pharmacological effects, including addiction, and design their products to provide pharmacologically active doses of nicotine. The FDA thus concluded that cigarettes and smokeless tobacco are subject to FDA jurisdiction because they contain a "drug", nicotine, and a "device" for delivering this drug to the body.

JAMA. 1997;277:405-409

ON AUGUST 28, 1996, President Clinton announced the final regulations of the U.S. Food and Drug Administration (FDA) restricting the sale and promotion of cigarettes and smokeless tobacco. The FDA's assertion of jurisdiction over tobacco products under the Federal Food, Drug, and Cosmetic Act (the Act) was the culmination of an exhaustive, 2 1/2-year investigation of tobacco products. This article explains the legal and scientific basis for this assertion of jurisdiction.

In asserting jurisdiction over cigarettes and smokeless tobacco, FDA relied on its authority to regulate drugs and devices. Under the relevant portion of the Act, a product is a "drug" or "device" if it is an article (other than food) "intended to affect the structure or any function of the body". When FDA last considered this issue, it declined to assert jurisdiction over cigarettes because it lacked evidence that cigarettes were intended to affect the structure or function of the body. Since that time, however, substantial new evidence became available to FDA. This evidence included the emergence of a scientific consensus that the nicotine in cigarettes and smokeless tobacco causes and sustains addiction, as well as the disclosure of thousands of pages of internal tobacco company documents

revealing that the tobacco manufacturers know that nicotine causes significant pharmacological effects, including addiction, and design their products to provide pharmacologically active doses of nicotine.

This new evidence demonstrated to FDA that (1) nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" and (2) these effects on the structure and function of the body are "intended" by the manufacturers. These findings, which are explained below, provided the basis for the agency's determination that cigarettes and smokeless tobacco are subject to FDA jurisdiction as products that contain a "drug", nicotine, and a "device" for delivering this drug to the body.

. . .effects on the structure and function of the body are "intended" by the manufacturers.

Effects On Structure and Function

The scientific evidence before FDA established that the nicotine delivered by cigarettes and smokeless tobacco has significant pharmacological effects on the structure and function of the body. First, this evidence showed that nicotine in cigarettes and smokeless tobacco causes and sustains addiction. As the U.S. Surgeon General has reported, nicotine exerts psychoactive (or mood altering) effects on the brain that motivate repeated, compulsive use of the substance. These pharmacological effects create dependence in the user. The pharmacological processes that cause this addiction to nicotine are similar to those that cause addiction to heroin and cocaine.

Second, scientific studies showed that nicotine in cigarettes and smokeless tobacco produces other important pharmacological effects on the central nervous system. Under some circumstances and doses, for instance, the nicotine has a sedating or tranquilizing effect on mood and brain activity. Under other circumstances and doses, the nicotine has a stimulant or arousal-inducing effect on mood and brain activity.

Third, as the U.S. Surgeon General also documented, nicotine in cigarettes and smokeless tobacco affects body weight.

The FDA found that these effects on the structure and function of the body are significant and quintessentially druglike. They are the same as the effects of other drugs that FDA has traditionally regulated, including stimulants, tranquilizers, appetite suppressants, and products, such as methadone, used in the maintenance of addiction. For these reasons, the agency concluded that cigarettes and smokeless tobacco "affect the structure or any function of the body" within the meaning at the Act.

The Issue Of Intent

Having established that nicotine in cigarettes and smokeless tobacco affects the structure and function of the body, the central question before the FDA became whether these effects of nicotine on the structure or function of the body are "intended" by the manufacturers. To answer this question, FDA was required to evaluate objectively all the relevant evidence of intent before the agency.

This evidence fell principally into 3 categories: (1) evidence that the pharmacological effects and uses of cigarettes and smokeless tobacco are foreseeable to a reasonable manufacturer; (2) evidence that consumers actually use cigarettes and smokeless tobacco predominantly for pharmacological purposes; and (3) evidence of the statements, research, and actions of the manufacturers themselves. The agency determined that, whether considered independently or cumulatively, this evidence demonstrated that cigarettes and smokeless tobacco are in fact "intended" to be used for pharmacological purposes.

Nicotine's Foreseeable Pharmacological Effects

Before 1980, when FDA last considered its jurisdiction over tobacco products, no major public health organization had determined that nicotine was an addictive drug. Today, however all major public health organizations in the United States and abroad with expertise in tobacco or drug addiction recognize that the nicotine delivered by cigarettes and smokeless tobacco is addictive. Since the 1980's, nicotine in tobacco products has been recognized as addictive by the American Psychiatric Association (1980), the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994). This scientific consensus is based on a wealth of

Continued on next page

Continued from page 15

epidemiologic and laboratory data establishing that tobacco users display the clinical symptoms of addiction and that nicotine has the characteristics of other addictive drugs.

It is also now well established that the nicotine in cigarettes and smokeless tobacco will cause, and be used for, other significant pharmacological effects, including its psychoactive or mood-altering effects in the brain. In addition, it is widely recognized today that nicotine plays a role in weight regulation, with substantial evidence demonstrating that cigarette smoking leads to weight loss.

The FDA found that this new scientific consensus made it foreseeable to any reasonable manufacturer that cigarettes and smokeless tobacco would cause addiction to nicotine and be used by consumers for pharmacological purposes, including satisfying their addiction. In light of the overwhelming scientific data and consensus, FDA concluded that the tobacco industry's public assertions that nicotine is not addictive were simply not credible.

The agency's finding that cigarettes and smokeless tobacco have foreseeable pharmacological effects has important legal significance. When Congress expanded the current definition of "drug" in 1938 to include products "intended to affect the structure or any function of the body," it was well understood that "[t]he law presumes that every man intends the legitimate consequences of his own acts". Consistent with this well-accepted legal principle, FDA's regulations provide that a product's intended pharmacological use may be established by evidence that the manufacturer "has knowledge of facts that would give him notice" that the product will be widely used for a pharmacological purpose, even if the product is not promoted for this purpose. Thus, the agency concluded that the tobacco manufacturers must be held to "intend" the foreseeable pharmacological uses of their products.

Consumer Use of Tobacco Products

A second and related basis for establishing that a product is intended to affect the structure or function of the body is evidence showing that consumers actually use the product for pharmacological purposes. In fact, courts have recognized that even in the absence of any evidence that the manufacturer has promoted the product for a pharmacological purpose, the product's intended use as a drug or device may be established solely by evidence showing that consumers use the product "predominantly" for pharmacological purposes.

In the case of cigarettes and smokeless tobacco, studies conducted since 1980 demonstrated to the agency that consumers do use these products "predominantly" for pharmacological purposes, including satisfying an addiction to nicotine. Major recent studies have concluded that 77% to 92% of smokers are addicted to nicotine in cigarettes. Similarly, the U.S. Department of Health and Human Services recently estimated that 75% of young regular users of smokeless tobacco are addicted to nicotine. A recent survey by the Centers for Disease Control and Prevention also showed that the majority of young consumers who use cigarettes or smokeless tobacco daily do so for mood alteration.

Thus, this evidence of actual consumer use provided an independent basis for FDA's conclusion that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

Manufacturer Statements, Research, and Actions

The third category of evidence considered by the agency was newly disclosed evidence showing that tobacco companies expect their products to be used by consumers for pharmacological purposes and have designed their products to be pharmacologically active. Although this evidence included 3 decades of tobacco industry statements, research, and actions, virtually all of it became available only recently as the result of FDA's investigation, congressional hearings, and other sources.

The evidence of the tobacco manufacturers' statements, research, and actions in the administrative record led FDA to make two central findings regarding the manufacturers' actual intent. First, FDA found that "manufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine. . . , and that consumers use their products primarily to obtain the pharmacological effects of nicotine."

This finding was based in part on evidence that showed that senior officials and researchers working for the tobacco manufacturers had for decades consistently described nicotine as a

pharmacologically active drug. For instance, the record showed that in internal documents tobacco company officials and researchers called nicotine "a very remarkable beneficent drug" (1962), "addictive" (1963), "a potent drug with a variety of physiological effects. . . [and] a habit-forming alkaloid" (1972), "a narcotic, tranquilizer, or sedative" (1976), "pharmacologically active in the brain" (1976), "the physiologically active component of smoke having the greatest consequence to the consumer" (1978), "a powerful pharmacological agent with multiple sites of action" (1980), "an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses" (1980), "a 'drug'" (1981),and "a physiologically active . . . substance . . . [that] alters the state of the smoker by becoming a neurotransmitter and a stimulant" (approximately 1992).

The agency's finding was also supported by repeated acknowledgements in the internal company documents that consumers use tobacco products to obtain the pharmacological effects of nicotine. These documents showed, for instance, that tobacco company researchers recognized that "the confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine" and that "without any question, the desire to smoke is based on the effect of nicotine on the body". The documents also showed that the tobacco company researchers' knowledge of the importance of nicotine was communicated to the highest levels of the companies. Thus, as early as 1969, Philip Morris' vice president for research and development told the Philip Morris board of directors that "the ultimate explanation for the perpetuated cigarette habit resides in the pharmacological effect of smoke upon the body of the smoker."

Second, FDA found that "manufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine." The FDA based this finding in part on industry documents that disclosed internal research to determine the dose of nicotine that must be delivered to provide "pharmacological satisfaction for the smoker," as well as estimates by industry scientists of the minimum and optimum doses of nicotine that tobacco products must deliver. As one former senior official at Philip Morris put it, "a key objective of the cigarette industry over the last 20-30 years" was "maintaining an acceptable and

Continued on next page

Our multi-million dollar state-of-the-art health care facility.

Every day, we provide health care to more families in their homes than just about anyone. Whether you're recovering from surgery, disabled or just need a little help to maintain your independence, our fully-qualified nurses will come to your house and take care of you. On a part-time, full-time or live-in basis. We even have our own two-way patient communication system, Interim In-Touch℠, so you'll always have someone to talk to, 24 hours a day. We're Interim® HealthCare, and we provide health care for the people you love. Give us a call.

Interim HEALTHCARE

SPRINGFIELD 734-6900 | NORTHAMPTON 586-7365 | GREENFIELD 774-2922 | PITTSFIELD 445-4500

Medicare Certified
JCAHO Accredited

Health Law and Ethics

Continued from page 17

pharmacologically active nicotine level" in low-tar cigarettes. The record before the agency showed that several methods of enhancing nicotine delivery are commonly used in the manufacture of commercial cigarettes. Tobacco blending to raise the nicotine concentration in low-tar cigarettes is common. According to the vice chairman and chief operating officer of Lorillard Tobacco Co, for instance, "the lowest 'tar' segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine." Another common technique for enhancing nicotine delivery in low-tar cigarettes is the use of filter and ventilation systems that by design remove a higher percentage of tar than nicotine. Yet a third type of nicotine manipulation is the addition of ammonia compounds that increase the delivery of "free" nicotine to smokers by raising the alkalinity or pH of tobacco smoke. These ammonia technologies are widely used within the industry. In the case of smokeless tobacco, the evidence before the agency showed that nicotine manipulation is accomplished through the use of chemicals that alter the pH of the smokeless tobacco. The FDA found that moist snuff brands that are marketed as "starter" brands have a low pH and consequently deliver a low level of "free" nicotine to the user, limiting the absorption of nicotine in the mouth. The low nicotine deliveries allow the new user to develop a tolerance to nicotine without experiencing adverse reactions such as nausea and vomiting. In contrast, moist snuff brands that are marketed to experienced users have a high pH and consequently deliver a high level of "free" nicotine to the user, increasing the amount of nicotine available for absorption. The increased nicotine deliveries provide sufficient nicotine to sustain the user's addiction. Consistent with this evidence, the internal company documents actually described tobacco products as vehicles for the delivery of nicotine. In these documents, for example, senior officials and researchers for the tobacco manufacturers expressly conceived of tobacco products as "a dispenser for a dose unit of nicotine," "[n]icotine delivery devices," "a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form," and "the means of providing nicotine dose in a metered fashion." Under the Act, these findings of the manufacturers' actual knowledge and product design provided a third independent basis for establishing that the manufacturers "intend" to affect the structure and function of the body. The plain meaning of "intend" includes "to have in mind" or "to design" for a particular use. As the agency's investigation of the tobacco company documents revealed, the manufacturers did both (1) "have in mind" the use of cigarettes for the particular purpose of delivering the pharmacological effects of nicotine and (2) "design" their products to provide these effects.

Tobacco Products Are Combination Products

Under the Act, products such as cigarettes and smokeless tobacco that are intended to affect the structure and function of the body can be either a "drug" under section 201(g)(1)(c), or a "device" under section 201(h)(3). The principal difference between a drug and a device is that a device "does not achieve its primary intended purposes through chemical action within or on the body... and ...is not dependent upon being metabolized." Since enactment of the Safe Medical Devices Act of 1990, products can also be regulated as "combinations" of a drug and a device. Examples of combination products include drug delivery systems such as nebulizers used by persons with asthma and transdermal patches. Based on the agency's findings regarding the pharmacological effects and intended uses of nicotine in cigarettes and smokeless tobacco, FDA concluded that the nicotine in these products is a "drug" under the Act. The FDA further found that cigarettes and smokeless tobacco are not simply packaged nicotine. The agency found that cigarettes are "a highly engineered product" with components such as the tobacco blend, the filter, and the ventilation system that "have been carefully designed to deliver controlled, pharmacologically active doses of nicotine to the smoker." Likewise, FDA found that the processed tobacco in smokeless tobacco functions "to deliver the nicotine to the cheek and gum tissue for absorption into the body." The FDA determined that these components of cigarettes and smokeless tobacco meet the statutory definition of a "device." Thus, FDA concluded that cigarettes and smokeless tobacco products are "combination products" under the Act.

The Tobacco Industry's Arguments

The tobacco industry made two principal arguments contesting FDA's assertion of jurisdiction.

Continued on page 20

MEDICAL SPACE AVAILABLE

Samuel D. Plotkin and Associates, Inc. is pleased to offer you the following medical suites available for immediate occupancy:

780 CHESTNUT STREET - SPRINGFIELD, MA

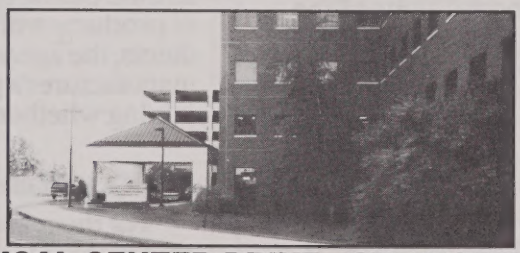
Across from Baystate Medical Center • $16.00 p.s.f. rent includes heat, air conditioning, electricity and parking • A generous build-out is included

- 2,006 square feet (former O.B.G.Y.N. practice)
- 1,107 square feet (former surgery practice)
- 500 square feet (former psychology practice)

125 LIBERTY STREET - SPRINGFIELD, MA

1/2 mile from Mercy Hospital and less than one mile from Baystate Medical Center • On site radiology, imaging, and laboratory • Best referral pattern in any non-hospital campus based medical building in the area • $16.00 p.s.f. rent includes heat, air conditioning, electricity and parking • A generous build-out allowance is included

- 550 square feet (first floor at lobby)
- 684 square feet (corner suite)
- 808 square feet (corner suite)
- 996 square feet
- 1,300 square feet
- 1,600 square feet sublet opportunity(first floor lobby)



*2 MEDICAL CENTER DRIVE - SPRINGFIELD, MA
BAYSTATE MEDICAL OFFICE BUILDING CONDOMINIUM

The areas premier medical office building • On site radiology, imaging, and laboratory • Excellent referral pattern • Located on Baystate Medical Center Campus

- 1,060 square feet for sale or lease - call for information
- 1,932 square feet for sale or lease - call for information

*occupants must be qualified users/affiliated with Baystate Medical Center

WE CAN HELP YOU CONTROL THE COST OF PROVIDING HEALTH CARE.
TO VIEW ANY OF THESE SUITES OR FOR FURTHER INFORMATION CONTACT DANIEL PLOTKIN AT 413/732-2158

SAMUEL D. PLOTKIN AND ASSOCIATES, INC.
Tower Square/1500 Main Street
P.O. Box 15449, Springfield, MA 01115

Continued from page 18

First, the industry asserted that the agency was barred from regulating tobacco products because FDA had previously taken the position that it did not have jurisdiction over tobacco products, causing Congress to enact alternative approaches to regulating these products, such as the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act. Historically, FDA has asserted jurisdiction over tobacco products when there is sufficient evidence before the agency to establish that the products in question are "intended" to affect the structure and function of the body. Over 30 years ago, for instance, FDA asserted jurisdiction over a brand of cigarettes that were intended to reduce body weight. In that case, the weight-reduction claims made by the manufacturer were sufficient evidence to allow the court to conclude that the cigarettes at issue were "obviously an article intended to affect the structure and/or function of the body." In the past, however, FDA did not regulate cigarettes and smokeless tobacco as a class of products, because in the absence of advertising promoting cigarettes and smokeless tobacco for weight loss or other pharmacological uses, FDA could not establish that these products were intended to affect the structure or function of the body. The FDA's recent assertion of jurisdiction is consistent with this approach. The reason FDA is now regulating cigarettes and smokeless tobacco as a class of products is that for the first time the evidence before the agency is sufficient to show that these products are in fact "intended" to affect the structure or function of the body. None of the statutes cited by the tobacco industry bar FDA from regulating cigarettes or smokeless tobacco once this intent has been demonstrated. For example, the narrow preemption provision in the Federal Cigarette Labeling and Advertising Act only restricts federal agencies from requiring "statement[s] relating to smoking and health...on any cigarette package." Second, the tobacco industry argued that the intended use of a product must be determined exclusively on the basis of the promotional claims made by the manufacturer. Under the industry's legal theory, unless tobacco products are labeled and advertised for sustaining nicotine addiction, altering mood, or regulating weight, they are not "intended" as drugs or devices. Thus, the industry urged FDA to disregard the evidence from internal company documents, as well as the evidence of the foreseeable and actual consumer uses of cigarettes and smokeless tobacco.

The FDA rejected this interpretation of the Act for several reasons. First, the industry's position is contrary to the plain language of the Act. The Act does not provide that only products 'promoted' to affect the structure or function of the body are drugs or devices. Rather, the Act provides that products "intended" to affect the structure or function of the body are drugs or devices. The ordinary meaning of "intend" permits a wide range of evidence to be considered in determining intent, including the types of evidence relied upon by FDA. Second, consistent with the plain meaning of "intend," the courts have concluded that FDA is "free to pierce . . . a manufacturer's misleading...labels to find actual therapeutic intent on the basis of objective evidence." The courts have thus recognized that FDA may consider many categories of evidence beyond the manufacturer's promotional claims, including evidence of the pharmacological effects of the product, the purposes for which consumers actually use the product, the medical use of the product, and how the product was formulated. Third, preserving FDA's authority to consider evidence of the pharmacological effects and uses of a product, as well as evidence of the manufacturer's knowledge and actions, is necessary for the protection of the public health. If promotional claims alone determined the intended use of a product, virtually any manufacturer of drugs or devices could avoid being required to demonstrate the safety and effectiveness of its product under the Act by simply refraining from making pharmacological claims for the product. For instance, under the tobacco industry's interpretation, a company could market a potent tranquilizer or an antidepressant for its "pleasurable" effect and thereby avoid FDA regulation. To protect the public from the unregulated distribution of products with pharmacologically active ingredients, the agency must be able to look beyond a manufacturer's promotional claims when determining whether to regulate such products.

CONCLUSION

For the reasons summarized above, FDA concluded that (1) the evidence before it demonstrated that cigarettes and smokeless tobacco are intended to sustain addiction and produce other pharmacological effects and (2) these products should therefore be regulated as "devices" intended to deliver the "drug" nicotine. This assertion of jurisdiction is the basis for one of the most important regulations in the agency's history: the Children's Tobacco Rule, a comprehensive approach to reducing cigarette and smokeless tobacco use by children by restricting their access to tobacco products and limiting the appeal of tobacco advertising to youth. ■

Are you prepared to accept a lower standard of living in retirement?

Probably not. But most do not realize that they'll still need 80% of their current income in retirement.

If you would like to start a retirement plan to help get yourself on track for retirement, or get a second opinion on your existing retirement portfolio, ***contact me today***.

Robert B. Mauterstock, Jr., CFP
78 Beaver Road, Suite 2C
Wethersfield, CT 06109
(860) 721-0343

LPL FINANCIAL SERVICES

Linsco/Private Ledger Member NASD/SIPC

SPRING INTO SAVINGS

GET THE MOST FOR YOUR SERVICES

ARE YOU TIRED OF DENIAL LETTERS FROM THE INSURANCE COMPANIES INCLUDING MEDICARE AND MEDICAID

LET C & S CLAIMS SERVICES TAKE AWAY YOUR LOSSES AND GIVE YOU THE PROFITS YOU DESERVE

- MEDICAL CLAIMS PROCESSING
- TRANSCRIPTION SERVICES
- BOOKEEPING SERVICES

C & S CLAIMS SERVICES
P.O. BOX 837
CHICOPEE, MA 01021

(413) 594-5106
OR
(413) 536-7922

Visiting Nurse Services

of Western Massachusetts

Visiting Nurse Services of Western Massachusetts offers a comprehensive range of home healthcare services for patients of all ages. From high-tech nursing to personal care - from Hospice to physical therapy - we've built our reputation on a 90-year tradition of excellence.

Formerly the Holyoke VNA

JCAHO Accreditation with Commendation
Certified for Medicare & Medicaid

330 Whitney Avenue, Suite 500
Holyoke, MA 01040

413/534.5691

New Members Welcome

Sharon M. Christie, M.D.
New England Dermatology
3455 Main Street
Springfield, MA 01107

Born: April 12, 1963
Medical: New York Medical College 1992
Internship: Baystate Medical Center 1992-1993
Residency: Roger Williams Medical Center/Brown University 1993-1996
Specialty: Dermatology

Katharine O. Freeman, M.D.
Springfield Anesthesia Service
P.O. Box 1330
Springfield, MA 01101

Born: May 10, 1962
Medical: University of Pennsylvania Medical School 1988
Internship: Children's Hospital of Philadelphia, PA 1988-1989
Residency: Children's Hospital of Philadelphia, PA 1989-1991 (Pediatrics)
Brigham & Women's Hospital 1991-1994 (Anesthesiology)
Specialty: Anesthesiology

Hani Kozman, M.D.
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199

Born: September 3, 1966
Premed: John Abbott College, Montreal, Canada 1983-1985
Medical: University of Sherbrooke, Quebec, Canada 1985-1989
Residency: University of Sherbrooke 1989-1992 (Family/Emergency Medicine)
East Virginia Medical School, Virginia 1992-1996 (Internal Medicine)
Fellowship: Baystate Medical Center 1996-1999 (Cardiology)
Specialty: Internal Medicine/Cardiology
Fellow

Jay Markham, M.D.
299 Carew Street
Springfield, MA 01104

Born: April 19, 1956
Medical: Albert Einstein College of Medicine, New York 1985
Internship: Rhode Island Hospital 1985-1986
Residency: Rhode Island Hospital 1986-1988
Fellowship: West Roxbury VA Medical Center, MA 1988-1990
St. Elizabeth's Hospital, MA 1990-1991
Specialty: Internal Medicine/Cardiology

Maher Toulaymat, M.D.
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199

Born: December 11, 1965
Medical: Damascus University School of Medicine 1989
Internship: Monmouth Medical Center, New Jersey 1993-1994
Residency: Baystate Medical Center 1994-Present
Specialty: Pathology
Resident

Wagdy Y. Zakhary, M.D.
Springfield Anesthesia Service
P.O. Box 1330
Springfield, MA 01101

Born: December 7, 1947
Medical: Cairo University Medical School, Egypt 1969
Internship: The Carney Hospital, Boston 1978-1979
Residency: Boston University/Boston City Hospital 1979-1981
Yale-New Haven Hospital, CT 1981-1982
Specialty: Anesthesiology

James Y. Chen, M.D.
Springfield Anesthesia Service
908 Allen Street
Springfield, MA 01118

Born: February 22, 1964
Medical: Tufts University School of Medicine 1992
Internship: Baystate Medical Center 1992-1993
Residency: Baystate Medical Center 1993-1996
Specialty: Anesthesiology

Aram V. Fereshetian, M.D.
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199

Born: July 24, 1953
Medical: American University of Beirut 1975-1980
Internship: American University of Beirut Medical Center 1979-1980
Residency: American University of Beirut Medical Center 1980-1982
Johns Hopkins Hospital 1982-1984 (Radiology)
Fellowship: Johns Hopkins Hospital 1984-1985 (Interventional Radiology)
Johns Hopkins Hospital 1985-1986 (Pediatric Radiology)
Specialty: Radiology, Cardiovascular Radiology, Interventional Radiology, Pediatric Radiology

RadhaKrishan Gupta, M.D.
Market Square Medical Associates
249 Exchange Street
Chicopee, MA 01013

Born: February 6, 1946
Medical: Gajra RAJA Medical College, Gwalior, India 1963-1971
Internship: J.A. Group of Hospitals/G.R. Medical College 1968-1970
Residency: Maulana Azad Medical College/Irwin and G.B. Pant Hospital, New Delhi, India 1972-1975
Mercy Hospital, Pittsburgh, PA 1982-1983
UMass Medical Center, Worcester, MA 1983-1984
Specialty: General Practice

Paul J. Helmuth, M.D.
Valley Medical Associates
125 Liberty Street
Springfield, MA 01103

Born: August 22, 1966
Medical: Northeast Ohio University College of Medicine 1992
Internship: Baystate Medical Center 1992-1993
Residency: Baystate Medical Center 1993-1996
Specialty: Internal Medicine/Pediatrics

Marilyn Li, M.D.
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199

Born: May 29, 1970
Premed: Brown University, Rhode Island 1988-1992
Medical: Brown University School of Medicine 1992-1996
Internship: Baystate Medical Center 1996-Present
Specialty: Internal Medicine/Pediatrics
Intern

Hospice Life Care

Hospice Life Care provides compassionate care to terminally ill patients and their families. Hospice's holistic approach to care seeks to make patients as comfortable as possible, and to manage symptoms so that their last days may be spent with dignity and quality. Services are provided primarily at home. A nursing home program is also available.

A program of Visiting Nurse Services of Western Massachusetts, Inc.

JCAHO Accreditation with Commendation

330 Whitney Avenue, Suite 400
Holyoke, MA 01040

413/533.3923

In Memoriam

Joseph M. Baker, M.D., Dr. Joseph M. Baker, 85, of Longmeadow and Williamsburg, one of the country's first plastic surgeons, died on March 10, 1997. He opened a private practice in Springfield in 1943, specializing in reconstructive and oral surgery. Born in Brattleboro, VT., he was a 1929 graduate of Brattleboro High School, Tufts College, the Harvard University Dental School in 1935, and the University of Vermont School of Medicine in 1940.

He trained at Worcester City Hospital , Mercy Hospital in Springfield, and Kings County Hospital in Brooklyn, NY.

He was one of the first 100 plastic surgeons to be certified, and the first associated with the Shriners Hospital for Children in Springfield. He performed more than 500 operations there.

He was a communicant of St. Mary's Church, and lived here from 1950.

He was a member of the New England Society of Plastic and Reconstructive Surgeons and the Hampden District Medical Society, and he was on the staffs at Mercy Hospital and Springfield Hospital (now Baystate Medical Center).

He conducted the State Crippled Children's Program at Mercy, and was a plastic surgery consultant at Holyoke Soldiers Home. He was appointed by Gov. John Volpe to serve on the Board of Registration in Medicine in Boston, and he was a Paul T. Harris fellow of the Springfield Rotary Club.

He also belonged to Longmeadow Country Club and the Vermont and Williamsburg Historical Societies, and was a tree farmer in Williamsburg.

His wife, Eileen S. (Sullivan) Baker, died in 1992.

He leaves two sons, Joseph M. Jr. and David G. of Rutland, VT.; two daughters, Frances B. Houser of East Longmeadow, and Martha B. Moran of Williamsburg; a sister, Margaret Concannon of Hopedale; nine grandchildren and two great-grandchildren. ■

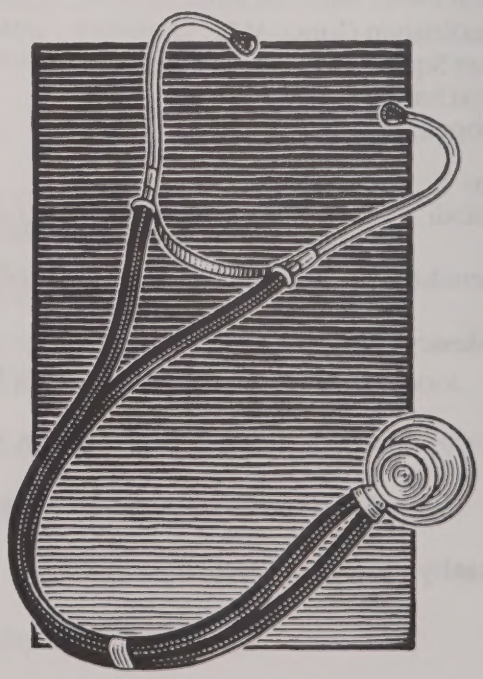
PRIMARY CARE PHYSICIANS

Department of Veterans Affairs Medical Center in Northampton, Massachusetts is seeking (2) two full time primary care physicians, for outpatient clinic positions.

Candidates should be BC/BE in either internal medicine or family practice. For one of these positions, Geriatric experience a plus. Regular hours. Excellent benefits. U.S. Citizenship is required. The Northampton Veterans Affairs Medical Center is located within a three hour drive from New York City and a two hour drive from Boston and Cape Cod. An Equal Opportunity Employer (EOE). Cultural, recreational, and educational opportunities abound.

Interested candidates should send CV to:

William Boutelle, M.D.
Chief of Staff (11)
V.A. Medical Center
421 North Main Street
Northampton, MA 01060-1288



Here's Our Agenda

It's simple. It's straightforward. And it represents the future of medicine. The American Medical Association presented to the Republican and Democratic leadership this agenda for the upcoming 105th Congress. Your AMA membership strengthens our voice in support of physicians and their patients. . . and will enhance our efforts to turn these goals into reality.

- **Patient Protections** Above all, preserve the ability of physicians to act as advocates for their individual patients. Do not allow insurers to "gag" physicians or withhold medically necessary treatments from their patients.
- **Medicare Reform** Make the Medicare program solvent. Expand patient choice of plans. Allow future growth rates that cover patients needs. Retain special protection for the vulnerable and elderly.
- **Medical Education and Research** Continue to support medical education and research so we can find cures for killers such as AIDS and cancer.
- **Public Health Problems** Expand prevention and treatment programs to combat AIDS, drug abuse, smoking and violence. These problems cost billions of dollars and millions of lives.
- **Liability Reform** Enact meaningful liability reform to ensure fair compensation to patients with legitimate claims while eliminating excessive malpractice awards that lead to defensive medicine.

Join or renew your membership in the AMA today — call 800 AMA-3211

American Medical Association

Physicians dedicated to the health of America

150 Years of Caring for the Country

1847 • 1997

• GET INVOLVED AND KEEP INFORMED • GET INVOLVED AND KEEP

INFORMED • GET INVOLVED AND KEEP INFORMED • GET INVOLVED AND KEEP

INFORMED • GET INVOLVED AND KEEP INFORMED • GET INVOLVED AND KEEP

THE
Hampden Hippocrat

We Need Your Input!

Share your ideas and opinions with us. We want your feedback regarding the content of our publication.. We are also looking for people to write articles or to be guest co-editors. Please take a moment to fill out this form and detach fold and mail to the HDMS office *or* you may fax to (413) 731-8990.

Thank you for your time.

1.

In this issue I liked....

_____

_____

_____

2.

I would have liked to see more...

_____

_____

_____

3.

I would like to be a *contributing writer* for...

❑ SPRING ❑ SUMMER ❑ WINTER ❑ FALL

4.

I would like to be a *guest co-editor* for...

❑ SPRING ❑ SUMMER ❑ WINTER ❑ FALL

Name _____ Position or Title _____

Company Name _____ Phone _____

Address _____

City _____ State _____ Zip Code _____

GET INVOLVED AND KEEP INFORMED • GET INVOLVED AND KEEP

OFFICE SPACE FOR RENT

IN

NEW PROFESSIONAL MEDICAL BUILDING

CENTRALLY LOCATED TO ALL AREA HOSPITALS

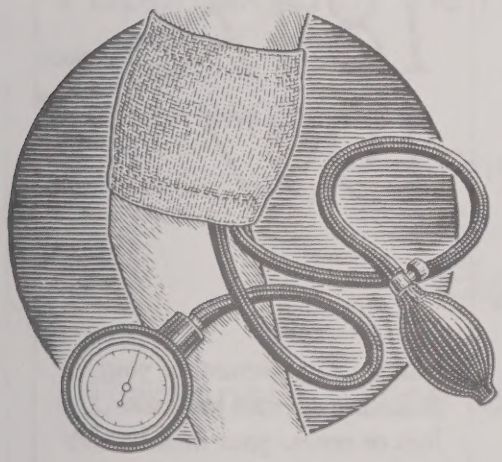
(Near Westfield & West Springfield Border)

AVAILABLE NOW

65 Springfield Road • Westfield, MA 01085

FOR MORE INFORMATION CALL:

413/562•7558



FULL AND PART TIME PHYSICIANS NEEDED

FOR

URGENT CARE CENTER IN SPRINGFIELD

Call Daniel Dress, M.D.

413/781•1812

In Memoriam

John J. Bandeian, M.D. (1912-1997)

Dr. Bandeian was born in Armenia in 1912. He lived through the turmoils that occurred later in that country. His father and several family members were killed. He emigrated to the United States with his mother as a teenager. He grew up in the greater Boston area. He received his undergraduate degree from Harvard University and his MD from Tufts. He completed internships at the Jersey City Medical Center and at the Massachusetts Memorial Hospital in Boston.

He subsequently received post-graduate training in general surgery, cancer surgery and GYN cancer surgery at the Pondville Cancer Hospital, The Beverly Hospital and the Massachusetts General Hospital. He was an assistant to Dr. Joseph V. Meigs at the Massachusetts General Hospital.

He entered practice in general surgery in Holyoke in 1948 and practiced continuously in that community until shortly before his death. He served primarily on the staff of the Providence Hospital where he continued to be active throughout his career.

Dr. Bandeian was President of the Hampden District Medical Society in 1971. At that time, he founded the Health Care Foundation of Western Massachusetts. He was also associated with the establishment of the Western Mass PSRO, a predecessor to the Mass Peer Review Organization that continues to operate today.

Dr. Bandeian was a Fellow of the American College of Surgeons, the AMA, the Mass Medical Society, the Trudeau Society, and the Hampden District Medical Society. He was a diplomat of the American Board of Surgery.

He will be missed by family, colleagues, and particularly his many loyal patients. ■

Lorne C. Smith, M.D.

Short Notes

Connelly Co-Edits Book

Dr. Neil Roy Connelly, Chair of the Anesthesiology Research Committee of the Department of Anesthesiology at Baystate Medical Center, has co-edited a textbook. The book, *Review of Clinical Anesthesia,* 2nd Ed. is published by Lippincott-Raven. The book is also one of eight texts of the CD ROM, *Interactive Anesthesia Library on CD ROM,* also published by Lippincott-Raven. ■

Letter To The Editor

Dear Doctor Glackin:

I became a shareholder in Health New England at its inception in 1985. When I retired from active practice nine years later, I sold back my share, as required by the contract.

Between the money received in 1994, this month and further payment promised, I will have received 1300% capital gains for just nine years of membership.

I am led to the conclusion, that one, two or all three of the following are true:

1) Physicians and other "providers" were underpaid.

2) Premiums were set too high.

3) Needed and appropriate services were withheld from patients.

Did I forget any possibilities?

Walter F. Tauber, M.D.

150 years of caring for the country 1847 - 1997

Make a commitment to your patients and your profession. Join or renew your membership in the AMA today.

American Medical Association
Physicians dedicated to the health of America

LB
personal service
since 1922

LESTER L. BURDICK, INC.

Loyalty Group Insurance

Disability Income Insurance

Group Term Renewable Life

Office Overhead Insurance

Payroll Deductions

- Sponsored by the Hampden District Medical Society.
- Insurance for:

  Physicians
  Spouses
  Eligible Employees
- Personal Service for over 75 Years.

CALL 1 - 800 - 959 - 9955

LB
personal service
since 1922

LESTER L. BURDICK, INC.

Loyalty Group Insurance

ONE CORPORATE DRIVE, ANDOVER, MA 01810

One System of Care
for Every Season of Life

With more than 5,000 employees, the Sisters of Providence Health System is dedicated to providing you, your family and your business comprehensive health care services for every season of life.

Children

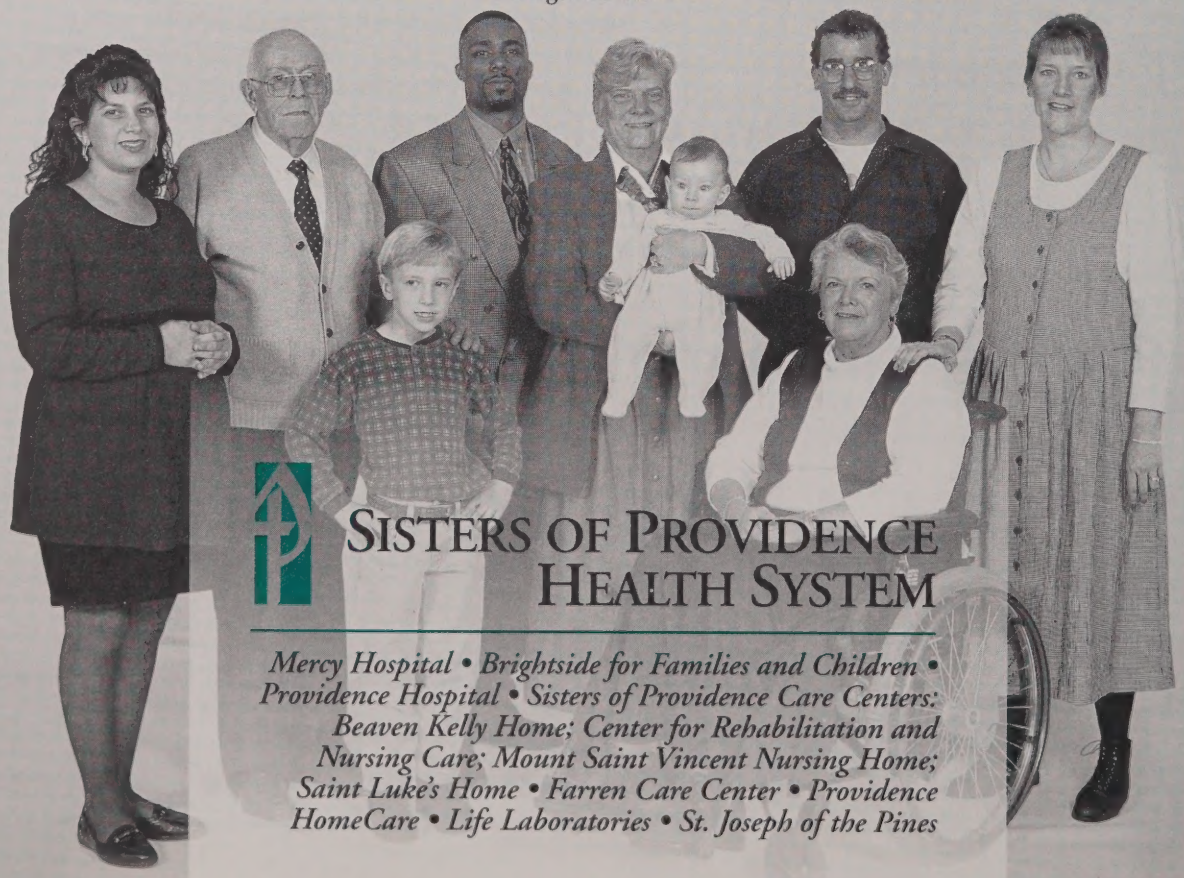
Adoption Services
Infant Hearing Evaluations
Maternity Services
Children's Rehabilitation
Mental Health Services
Pediatric Hospital Care
Prenatal Care
Substance Abuse Treatment and Prevention

Adults

Emergency Services
HIV Services
Laboratory Services
Mental Health Services
Oncology
Outpatient Services
Radiology
Rehabilitation
Substance Abuse Treatment and Prevention
Surgical Services

Seniors

Adult Day Care
Alzheimer's Program
Assisted Living
Home Care
Rehabilitation
Residential Living
Respite Care
Skilled Nursing Care



SISTERS OF PROVIDENCE HEALTH SYSTEM

Mercy Hospital • Brightside for Families and Children • Providence Hospital • Sisters of Providence Care Centers: Beaven Kelly Home; Center for Rehabilitation and Nursing Care; Mount Saint Vincent Nursing Home; Saint Luke's Home • Farren Care Center • Providence HomeCare • Life Laboratories • St. Joseph of the Pines